

What is claimed is:

1. A method of treatment or prophylaxis of an inflammatory bowel disease in a subject in need of said treatment or prophylaxis, said method comprising:

5 providing at least one antiviral selected from the group consisting of antivirals active against Herpes viruses and pharmaceutically acceptable salts thereof; and

administering the antiviral to the subject in an amount effective to treat or prevent the inflammatory bowel disease, with the proviso that the method excludes administration of an anti-inflammatory agent selected from the group consisting of salicylates and  
10 salicylate prodrugs.

2. The method of claim 1, wherein the antiviral is selected from the group consisting of acyclovir, acyclovir sodium, brivudine, cidofovir, famciclovir, foscarnet, ganciclovir, penciclovir, trifluridine, valacyclovir, valgancyclovir, and mixtures thereof.

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3. The method of claim 1, wherein the antiviral is acyclovir sodium.

4. The method of claim 1, further providing at least one additional agent effective against an inflammatory bowel disease, wherein the antiviral and the additional  
20 agent are administered to said subject simultaneously as an admixture, separately and simultaneously, or separately in any order.

5. The method of claim 4, wherein the additional agent is one or more agents selected from any of the following groups:

25 (i) an agent selected from the group consisting of corticosteroids, mercaptopurine, azathioprine, methotrexate, cyclosporine and tacrolimus;

(ii) an additional antiviral selected from the group consisting of antivirals other than antivirals active against Herpes viruses and other than pharmaceutically acceptable salts of antivirals active against Herpes viruses thereof; and

(iii) an agent selected from the group consisting of nitric oxide releasing steroid  
5 derivatives, nitric oxide-releasing salicylates, enzyme inhibitors, p38 kinase inhibitors,  $\alpha 4$   
integrin inhibitors, protein and peptide inhibitors of TNF, antisense inhibitors of ICAM-1,  
NF-kappa-B inhibitors, neurokinin-1 antagonists, antisense inhibitors of TNF, monoclonal  
antibodies or antibody fragments against TNF- $\alpha$ , monoclonal antibodies or antibody  
fragments against IL-12, monoclonal antibodies or antibody fragments against IL-6,  
10 monoclonal antibodies or antibody fragments against CD40, monoclonal antibodies or  
antibody fragments against  $\alpha 4\beta 7$  integrin receptor, monoclonal antibodies or antibody  
fragments against  $\alpha 4$  integrin, keratinocyte growth factor, interferon, flavonoids,  
glucocorticoids, analogues of GLP-2, small molecule glutathione peroxidase mimics, small  
molecule phosphodiesterase IV inhibitors, thiazole derivatives inhibiting superoxide  
15 production by human neutrophils, 5-lipoxygenase inhibitors, L-selectin antagonists,  
omega-3 unsaturated fatty acids, bactericidal/permeability-increasing (BPI) agents, guan-  
ylhydrazone compounds, selective apoptotic antineoplastic drugs, thalidomide, and  
recombinant human interleukin-11.

20           6.       The method of claim 5, wherein the corticosteroids are systemically inactive  
corticosteroids.

             7.       The method of claim 6, wherein the corticosteroids are selected from the  
group consisting of budesonide, fluticasone and pharmaceutically acceptable salts thereof.

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             8.       The method of claim 6, wherein the corticosteroids are formulated with an  
enteric coating.

9. The method of 5, wherein the additional antiviral of group (ii) is selected from the group consisting of abacavir, adefovir, amantadine, amprenavir, atazanavir, capravirine, delavirdine, didanosine, efavirenz, emivirin, emtricitabine, enfurvirtide, fosamprenavir, idoxuridine, indinavir, lamivudine, lopinavir, memantine, mozenavir, nelfinavir, nevirapine, oseltamivir, rimantidine, pentafuside, ritonavir, saquinavir, stavudine, tenofovir, tipranavir, zalcitabine, zanamivir, and zidovudine.

10. The method of claim 4, wherein the additional agent is infliximab.

10 11. The method of claim 4, wherein the antiviral active against a Herpes virus is acyclovir sodium and the additional agent is infliximab.

12. The method of claim 1 or 4, wherein the administration comprises parenteral administration, oral administration, inhalation, topical administration, transdermal administration, rectal administration, continuous infusion, or administration with an osmotic pump or a sustained release implant.

13. The method of claim 1, wherein the step of administering comprises orally administering the antiviral in a dose between about 200 mg to about 5 g per day for about 1 week to 12 months.

14. The method of claim 13, wherein the step of administering comprises orally administering the antiviral in a dose between about 200 mg to about 5 g per day for about 1 week to 4 weeks.

15. The method of claim 4, wherein the step of administering comprises orally administering to the subject for a period between about 1 week to 12 months (a) the

antiviral in a dose between about 200 mg to about 5 g per day and (b) the additional agent in an amount that is between about half the dosage and the same dosage of the additional agent which, when administered alone, is effective to treat or prevent the inflammatory bowel disease.

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16. The method of claim 4, wherein the step of administering comprises orally administering about 250 mg of the antiviral and about 3 mg of the additional agent.

17. The method of claim 16, wherein the antiviral and the additional agent are  
10 formulated in separate dosage forms.

18. The method of claim 17, wherein the antiviral is famciclovir and the additional agent is budesonide.

19. The method of claim 18, wherein the famciclovir and the budesonide are  
15 administered in parallel.

20. The method of claim 18, wherein the budesonide is formulated with an enteric coating.

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21. The method of claim 4, wherein the step of administering comprises orally administering to the subject for a period between about 1 to 4 weeks (a) the antiviral in a dose between about 200 mg to about 5 g per day and (b) the additional agent in an amount that is between about half the dosage and the same dosage which, when the additional agent is administered alone, is effective to treat or prevent said inflammatory bowel  
25 disease.

22. The method of claim 1, wherein the step of administering comprises intravenously administering for a period between about seven to ten days an intravenous infusion of the antiviral in a dose between about 5 to about 15 mg/kg body weight of the subject over a period of 60 minutes every six to eight hours.

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23. The method of claim 1, wherein the disease is selected from the group consisting of pseudomembranous colitis, hemorrhagic colitis, hemolytic-uremic syndrome colitis, collagenous colitis, ischemic colitis, radiation colitis, drug and chemically induced colitis, diversion colitis, ulcerative colitis, irritable bowel syndrome, irritable colon syndrome and Crohn's disease.

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24. The method of claim 23 wherein said Crohn's disease is selected from the group consisting of active Crohn's disease, refractory Crohn's disease, and fistulizing Crohn's disease.

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25. The method of claim 1, wherein the subject is a human.

26. A medicament against an inflammatory bowel disease, comprising one or more antivirals in combination with one or more additional agents active against the inflammatory bowel disease for administration to a mammal simultaneously in admixture, separately and simultaneously, or separately in any order, wherein the antiviral is in an amount effective to treat or prevent the inflammatory disease and comprises one or more antivirals selected from the group consisting of antivirals active against Herpes viruses and pharmaceutically acceptable salts thereof, with the proviso that the medicament excludes anti-inflammatory agents selected from the group consisting of salicylates and salicylate prodrugs.

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27. The medicament of claim 26, wherein the antiviral is selected from the group consisting of acyclovir, acyclovir sodium, brivudine, cidofovir, famciclovir, foscarnet, ganciclovir, penciclovir, trifluridine, valacyclovir, valgancyclovir, and mixtures thereof.

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28. The medicament of claim 26, wherein the antiviral is acyclovir sodium.

29. The medicament of claim 26, wherein the additional agent is one or more agents selected from any of the following groups:

10 (i) an agent selected from the group consisting of corticosteroids, mercaptopurine, azathioprine, methotrexate, cyclosporine and tacrolimus;

(ii) an antivirals other than antivirals active against Herpes viruses and other than pharmaceutically acceptable salts of antivirals active against Herpes viruses; and

15 (iii) agents selected from the group consisting of nitric oxide releasing steroid derivatives, nitric oxide-releasing salicylates, enzyme inhibitors, p38 kinase inhibitors,  $\alpha$ 4 integrin inhibitors, protein and peptide inhibitors of TNF, antisense inhibitors of ICAM-1, NF-kappa-B inhibitors, neurokinin-1 antagonists, antisense inhibitors of TNF, monoclonal antibodies or antibody fragments against TNF- $\alpha$ , monoclonal antibodies or antibody fragments against IL-12, monoclonal antibodies or antibody fragments against IL-6,  
20 monoclonal antibodies or antibody fragments against CD40, monoclonal antibodies or antibody fragments against  $\alpha$ 4 $\beta$ 7 integrin receptor, monoclonal antibodies or antibody fragments against  $\alpha$ 4 integrin, keratinocyte growth factor, interferon, flavonoids, glucocorticoids, analogues of GLP-2, small molecule glutathione peroxidase mimics, small molecule phosphodiesterase IV inhibitors, thiazole derivatives inhibiting superoxide  
25 production by human neutrophils, 5-lipoxygenase inhibitors, L-selectin antagonists, omega-3 unsaturated fatty acids, bactericidal/permeability-increasing (BPI) agents, guanyl-hydrazone compounds, selective apoptotic antineoplastic drugs, thalidomide, and recombinant human interleukin-11.

30. The medicament of claim 29, wherein the additional agent is a systemically inactive corticosteroid.

31. The medicament of claim 30, wherein the corticosteroid is budesonide,  
5 fluticasone, or pharmaceutically acceptable salts thereof.

32. The medicament of claim 30, wherein the corticosteroid is formulated with an enteric coating for oral administration.

10 33. The medicament of claim 29, wherein the antiviral of group (ii) is selected from the group consisting of abacavir, adefovir, amantadine, amprenavir, atazanavir, capravirine, delavirdine, didanosine, efavirenz, emivirin, emtricitabine, enfurvirtide, fosamprenavir, idoxuridine, indinavir, lamivudine, lopinavir, memantine, mozenavir, nelfinavir, nevirapine, oseltamivir, rimantidine, pentafuside, ritonavir, saquinavir,  
15 stavudine, tenofovir, tipranavir, zalcitabine, zanamivir, zidovudine and pharmaceutically acceptable salts thereof.

34. The medicament of claim 29, wherein the agent is infliximab.

20 35. The medicament of claim 29, wherein the antiviral is acyclovir sodium and said additional agent is infliximab.

36. The medicament of claim 26 formulated for oral administration.

25 37. The medicament of claim 36, comprising the antiviral in an amount between about 200 mg and 5 grams.

38. The medicament of claim 26 formulated as an intravenous infusion solution.

39. The medicament of claim 38, comprising about 109.8 mg of the antiviral per 100 mL of infusion solution.

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40. The medicament of claim 39, wherein said antiviral is acyclovir sodium.

41. The medicament of claim 38, comprising about 109.8 mg of the antiviral per 100 mL of infusion solution and about 100 mg of the additional agent per 100 mL of  
10 infusion solution.

42. The medicament of claim 41, wherein said antiviral is acyclovir sodium and said additional agent is infliximab.

15 43. The medicament of claim 38, wherein the antiviral and the additional agent are formulated in separate infusion solutions for separate but simultaneous administration.

44. The medicament of claim 36, comprising about 250 mg of the antiviral and about 3 mg of the additional agent.

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45. The medicament of claim 44, wherein the antiviral and the additional agent are formulated in separate dosage forms.

25 46. The medicament of claim 45, wherein the antiviral is famciclovir and said additional agent is budesonide.



47. The medicament of claim 46, wherein the famciclovir and the budesonide are administered in parallel.

48. The medicament of claim 46, wherein the budesonide is formulated with an enteric coating.

49. The medicament of claim 26, wherein said medicament is formulated for intravenous administration, parenteral administration, oral administration, inhalation, topical administration, transdermal administration, rectal administration, continuous infusion, or administration with an osmotic pump or a sustained release implant.

50. The medicament of claim 26, wherein the disease is selected from the group consisting of pseudomembranous colitis, hemorrhagic colitis, hemolytic-uremic syndrome colitis, collagenous colitis, ischemic colitis, radiation colitis, drug and chemically induced colitis, diversion colitis, ulcerative colitis, irritable bowel syndrome, irritable colon syndrome and Crohn's disease.

51. The medicament of claim 51, wherein said Crohn's disease is selected from the group consisting of active Crohn's disease, refractory Crohn's disease, and fistulizing Crohn's disease.

52. Use of one or more antivirals selected from the group consisting of antivirals active against Herpes viruses and pharmaceutically acceptable salts thereof for the preparation of a medicament against inflammatory bowel disease, with the proviso that the use excludes the use of anti-inflammatory agents selected from the group consisting of salicylates and salicylate prodrugs.

53. The use according to claim 53, wherein the antiviral is selected from the group consisting of acyclovir, acyclovir sodium, brivudine, cidofovir, famciclovir, foscarnet, ganciclovir, penciclovir, trifluridine, valacyclovir, valgancyclovir, and mixtures thereof.

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54. The use according to claim 53, wherein the antiviral is used in combination with at least one additional agent effective against inflammatory bowel disease selected from any of the following groups:

(i) an agent selected from the group consisting of corticosteroids, mercaptopurine, azathioprine, methotrexate, cyclosporine and tacrolimus;

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(ii) an antiviral other than antivirals active against Herpes viruses and other than pharmaceutically acceptable salts of antivirals active against Herpes viruses; and

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(iii) an agent selected from the group consisting of nitric oxide releasing steroid derivatives, nitric oxide-releasing salicylates, enzyme inhibitors, p38 kinase inhibitors,  $\alpha 4$  integrin inhibitors, protein and peptide inhibitors of TNF, antisense inhibitors of ICAM-1, NF-kappa-B inhibitors, neurokinin-1 antagonists, antisense inhibitors of TNF, monoclonal antibodies or antibody fragments against TNF- $\alpha$ , monoclonal antibodies or antibody fragments against IL-12, monoclonal antibodies or antibody fragments against IL-6, monoclonal antibodies or antibody fragments against CD40, monoclonal antibodies or antibody fragments against  $\alpha 4\beta 7$  integrin receptor, monoclonal antibodies or antibody fragments against  $\alpha 4$  integrin, keratinocyte growth factor, interferon, flavonoids, glucocorticoids, analogues of GLP-2, small molecule glutathione peroxidase mimics, small molecule phosphodiesterase IV inhibitors, thiazole derivatives inhibiting superoxide production by human neutrophils, 5-lipoxygenase inhibitors, L-selectin antagonists, omega-3 unsaturated fatty acids, bactericidal/permeability-increasing (BPI) agents, guanyl-hydrazone compounds, selective apoptotic antineoplastic drugs, thalidomide, and recombinant human interleukin-11.